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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,538	03/07/2002	Deb K. Chatterjee	0942.5250001	8240

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,538	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-15,18-26,31-34,36,37 and 43-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,16,17,27-30,35,38-42 and 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/02, 8/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election of Group IV, Claims 1, 5, 16, 17, 27-30, 35, 38-42, and 51-54. in the reply filed on 10/4/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2-4, 6-15, 18-26, 31-34, 36, 37, and 43-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 10/4/04.

Claims 1, 16, 17, 29, 30, 35, 38-42, and 51-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of *in vitro* protein or nucleic acid synthesis systems which comprise a genus of cell extracts having reduced activity of any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or formation of phosphodiester bonds, inhibitors of any enzyme that

catalyzes hydrolysis of high energy phosphate bonds, inhibitors of any enzyme that catalyzes hydrolysis of phosphodiester bonds or inhibitors of any enzyme that catalyzes formation of high energy phosphate bonds. The specification teaches the structure of only a single representative species of such cell extracts and a single representative species of an inhibitor of the hydrolysis of phosphodiester bonds. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having reduced activity of any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or formation of phosphodiester bonds or inbiting any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or formation of phosphodiester bonds. Furthermore, while the art clearly provides knowledge of many species of cell extracts having reduced activity of any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or formation of phosphodiester bonds and species of inhibitors of any enzyme that catalyzes hydrolysis of high energy phosphate bonds, inhibitors of any enzyme that catalyzes hydrolysis of phosphodiester bonds or inhibitors of any enzyme that catalyzes formation of high energy phosphate bonds, the skilled artisan would clearly not expect any species having

these functions to be useful in a protein or nucleic acid synthesis system. Clearly many inhibitors of polymerases or inhibitors of the hydrolysis of high-energy phosphate bonds would not be useful in transcription and/or translation systems as both of these functions are essential for transcription and translation. The specification fails to provide characteristics for selecting those species having these functions which would be useful as described from those species which would not be so useful. Similarly many cell extracts having reduced activity of any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or formation of phosphodiester bonds would also not be useful in such systems and the specification fails to teach characteristics for selecting those extracts which would be useful as described from those which would not be so useful. Furthermore, the genus of cell extracts encompassed further lacks description as the specification fails to teach sufficient structural characteristics of the cells for one of skill in the art to make any species within the scope of the claims. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan

would recognize that applicants were in possession of the claimed invention.

Claims 1, 16, 17, 29, 30, 35, 38-42, and 51-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* transcription and/or translation systems comprising one or more nuclease inhibitors or at least two sources of chemical energy for synthesis, does not reasonably provide enablement for *in vitro* transcription and/or translation systems comprising any cell extracts having reduced activity of any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or formation of phosphodiester bonds, any inhibitor of any enzyme that catalyzes hydrolysis of high energy phosphate bonds, any inhibitor of any enzyme that catalyzes hydrolysis of phosphodiester bonds or any inhibitor of any enzyme that catalyzes formation of high energy phosphate bonds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

These claims are directed to a genus of *in vitro* protein or nucleic acid synthesis systems which comprise a genus of cell extracts having reduced activity of any enzyme that catalyzes hydrolysis of high energy phosphate bonds or hydrolysis or

formation of phosphodiester bonds, inhibitors of any enzyme that catalyzes hydrolysis of high energy phosphate bonds, inhibitors of any enzyme that catalyzes hydrolysis of phosphodiester bonds or inhibitors of any enzyme that catalyzes formation of high energy phosphate bonds. However the specification each only a very limited number of such extracts or inhibitors. Furthermore, the vast majority of such extracts and inhibitors could not be reasonably expected to be useful in an *in vitro* transcription translation system as such systems require these functions for activity. The specification provides little guidance for the selection of those inhibitors/cell extracts which can be successfully used from those which cannot. Furthermore, the specification provides virtually no guidance for the skilled artisan with regard to making the enormous scope of cell extracts encompassed by the instant claims. Producing a cell extract with reduced activity of any protein requires detailed knowledge of the structure of the genes encoding that protein and/or methods of regulating the activity of the specific protein of interest. As such production and use of the entire scope of *in vitro* protein or nucleic acid synthesis systems claimed would be well beyond the bounds of routine experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 16, 29, 30, 35, 38-40, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Spirin et al. (Reference AT12 of applicant's IDS)

Spirin et al. teach *E. coli* and wheat germ *in vitro* translation systems comprising human placental ribonuclease inhibitor and a template RNA as well as several energy sources (i.e., ATP, GTP, and PEP or creatine phosphate) and thus anticipates all of the instant claims.

Claims 1, 5, 16, 17, 29, 30, 35, 38-42, and 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Beckler (US Patent 5,665,563).

Beckler teach rabbit reticulocyte and wheat germ *in vitro* coupled transcription/translation systems (see Example 1) comprising RNasin and a template DNA as well as several energy

sources (i.e., ATP, GTP, and creatine phosphate) as well as kits comprising all components of the coupled transcription/ translation systems (see column 9, lines 14-28) and thus anticipates all of the instant claims.

Claims 1, 5, 16, 17, 29, 30, 35, 38-42, and 51-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Kudlicki et al. (US Patent 6,664,379).

Kudlicki et al. teach *in vitro* reverse transcription, transcription, translation and coupled transcription/ translation systems comprising multiple nuclease inhibitors including inhibitors of DNases and RNases, a template DNA or RNA and energy sources as well as kits comprising all components of the systems (see column 6, lines 24-34) and thus anticipates all of the instant claims.

Claims 1, 16, 29, 30, 39-40, and 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Pratt (1984).

Pratt. teach *E. coli* coupled transcription/translation systems comprising an extract of an *E. coli* strain having a mutation in the *recB* gene (see pages 200-201) such that the extract exhibits a lack of the RecBCD exonuclease (also called exonuclease V) and a template DNA as well as several energy sources (i.e., ATP, GTP, and PEP) and thus anticipates all of the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Spirin et al. (Reference AT12 of applicant's IDS) or Pratt (1984).

Spirin et al. and Pratt are discussed above. Spirin et al. and Pratt do no specifically teach the provision of the disclosed systems in a kit. However, the it would have been obvious to provide the components of the system together in a packaged system as the provision of *in vitro* transcription and/or translation systems in kit form is well known in the art in order to provide added convenience to one utilizing the system.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (1984) in view of Yu et al. (Reference AR14 of applicant's IDS).

Pratt. teach *E. coli* coupled transcription/translation systems comprising an extract of an *E. coli* strain having a mutation in the *recB* gene (see pages 200-201) such that the extract exhibits a lack of the RecBCD exonuclease (also called exonuclease V). This transcription/translation is disclosed as particularly useful for linear DNA templates as these type of templates are particularly susceptible to degradation by the RecBCD exonuclease. Pratt however teach that these strains produce systems with high levels of background synthesis due to large amounts of contaminating chromosomal fragments or require an extended pre-incubation step (see pages 200-201).

Yu et al. teach that mutant *recBCD* strains have been used to prevent the rapid degradation of linear DNAs but that such strains lacking the RecBCD exonuclease are extremely poor growing. Yu et al. teach that one can alternatively inhibit the RecBCD exonuclease using the lambda phage Gam protein.

Therefore, it would have been obvious to one of ordinary skill in the art to replace the use of the *recB E. coli* strain used by Pratt et al. with a wild type *E. coli* strain (such as the MRE600 strain disclosed by Pratt as being the preferred

strain for preparation of the S30) and to include the lambda phage Gam protein in the transcription/translation to inhibit the degradation of linear template DNAs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty
Primary Examiner
Art Unit 1652